

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

ALASKA ELECTRICAL PENSION FUND, CITY  
OF SARASOTA FIREFIGHTERS' PENSION  
FUND, INTERNATIONAL UNION OF  
OPERATING ENGINEERS LOCAL 132 PENSION  
PLAN, NEW ENGLAND HEALTH CARE  
EMPLOYEES PENSION FUND, CHEMICAL  
VALLEY PENSION FUND OF WEST VIRGINIA,  
and PACE INDUSTRY UNION-MANAGEMENT  
PENSION FUND, On Behalf of Themselves and All  
Others Similarly Situated,

Plaintiffs,

v.

PHARMACIA CORPORATION, FRED  
HASSAN, G. STEVEN GEIS, CARRIE COX, and  
PFIZER INC.,

Defendants.

03-CV-1519 (AET)  
(Consolidated)

PUTATIVE CLASS  
ACTION

**ORAL ARGUMENT  
REQUESTED**

DOCUMENT FILED  
ELECTRONICALLY

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR  
CROSS-MOTION TO STRIKE AND IN OPPOSITION TO PLAINTIFFS'  
"MOTION TO SEAL"**

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Defendants Pharmacia Corporation (“Pharmacia”), Pfizer Inc. (“Pfizer”), Fred Hassan, G. Steven Geis and Carrie Cox (collectively, the “Defendants”) submit this memorandum of law in support of their cross-motion (1) to strike the following new materials and arguments submitted by Plaintiffs in support of their motion for class certification *for the first time* with their reply memorandum of law (“Pls’ Reply” or “Plaintiffs’ Reply”): (a) the purported expert declaration of Scott D. Hakala (the “Hakala Declaration”), and the portions of Plaintiffs’ Reply that present arguments based on the Hakala Declaration, (b) the purported expert declaration of James M. Wright, M.D. (the “Wright Declaration”), and the portions of Plaintiffs’ Reply that present arguments based on the Wright Declaration and (c) other (wholly irrelevant) documents (the “Confidential Documents,” described below) also submitted for the first time on Plaintiffs’ Reply; or (2) in the alternative, for leave to file surreply submissions in order to respond to the foregoing new materials. Defendants also submit this memorandum of law in opposition to the relief sought by Plaintiffs in a document technically entitled “Motion to Seal” the Confidential Documents, but in which Plaintiffs actually ask this Court to remove the confidentiality protection currently afforded these Documents.

### **PRELIMINARY STATEMENT AND BACKGROUND**

On April 3, 2006, Plaintiffs filed a motion for class certification consisting of boilerplate assertions devoid of evidentiary support as to the propriety of certifying a class. Except for Plaintiffs’ counsels’ firm resumes and certain of Pharmacia’s filings with the Securities and Exchange Commission (“SEC”), no



evidence accompanied the Motion. Instead, on reply, Plaintiffs have *for the first time* (and thus improperly) submitted hundreds of pages of documents, as well as two purported expert declarations, in a belated attempt to meet their burden to demonstrate that a class should be certified. All these newly submitted materials and the arguments premised on such materials should be stricken, or, alternatively, Defendants should be granted the opportunity to respond to these materials in a surreply.

Plaintiffs seek to certify a class consisting of all persons who purchased or otherwise acquired Pharmacia securities during the period April 17, 2000 to May 31, 2002. In Defendants' opposition to Plaintiffs' Motion ("Defendants' Brief"), Defendants established that Plaintiffs failed to submit any evidence and, thus, failed to meet their burden to establish compliance with the requirements of Fed. R. Civ. P. 23, including that issues common to the class predominate over individual issues, as required by Fed. R. Civ. P. 23(b).<sup>1</sup> Defendants also established that if a class is certified, the only appropriate class period can be from September 13, 2000 to February 6, 2001.

On reply, Plaintiffs have made new arguments based on new materials submitted for the first time on reply, in an eleventh-hour effort to meet their burden on class certification. But it is axiomatic that a movant cannot in reply papers make new arguments based on newly proffered materials. Were it otherwise, movants routinely would "sandbag" their adversaries (as Plaintiffs here are attempting to do) by introducing new materials and arguments on reply and

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<sup>1</sup> Defendants also demonstrated that Plaintiffs had failed to proffer evidence sufficient to meet their burden to demonstrate typicality and adequacy of representation, as also required by Fed. R. Civ. P. 23.

thereby unfairly depriving their adversaries of the opportunity to respond. For this reason, courts routinely strike new arguments and evidence submitted for the first time on reply. *See infra* at 4-5. The same result should be reached here, and this Court should strike Plaintiffs' arguments and related documents – the Hakala Declaration, the Wright Declaration and the Confidential Documents along with those portions of Plaintiffs' Reply that present arguments based on these materials (or grant Defendants leave to file a surreply). *See* Point I.A.

In addition, the Confidential Documents, which were produced by Defendants in the course of discovery, should be stricken on the additional ground that they are irrelevant and unnecessary to the motion for class certification and, therefore, are being proffered in violation of Local Rules 5.2 and 7.1(b)(3). Local Rule 7.1(b)(3), which governs motions filed electronically, requires compliance with this Court's Electronic Case Filing Policies and Procedures, which provide that "sensitive information should not be included in any document filed with the court *unless such inclusion is necessary and relevant to the case.*" ECF 18 (emphasis added); L.Civ.R. 5.2, n.18. As discussed below, the Confidential Documents should be stricken under Local Rules 5.2 and 7.1(b)(3). *See* Point I.B.

Finally, if the Court does not strike the Confidential Documents, then the documents should be filed under seal. Such a result is appropriate because these Documents have been designated confidential under the Protective Order entered in this case, which permits parties to designate "sensitive information" as confidential. The Confidential Documents consist of non-public, internal Pharmacia emails and draft meeting minutes that reflect back-and-forth discussion and analysis of scientific data and upcoming meetings with the Food and Drug

Administration (“FDA”). Such materials are precisely the type of non-public information, which discloses a company’s internal operations and deliberations, that was intended to be maintained as confidential under the Protective Order. *See* Point II.

## **ARGUMENT**

### **POINT I**

#### **PLAINTIFFS’ NEW MATERIALS AND THE ARGUMENTS BASED ON SUCH NEW MATERIALS SHOULD BE STRICKEN**

##### **A. Materials Purportedly Supporting A Motion Cannot Be Submitted For The First Time On Reply**

It is axiomatic that “[a] moving party may not raise new issues and present new factual materials in a reply brief that it should have raised in its initial brief.” *Ballas v. Tedesco*, 41 F. Supp. 2d 531, 533 n.2 (D.N.J. 1999). “The rationale for this rule is self-evident because the local rules do not permit sur-reply briefs, *see* [L. Civ. R. 7.1(d)(6)], a party opposing [the motion] has no opportunity to respond to newly minted arguments contained in reply briefs.” *Bayer A.G. v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705, 716 (D.N.J. 2001), *aff’d*, 301 F.3d 1306 (Fed. Cir. 2002).

*M.D. On-Line, Inc. v. WebMD Corp.*, No. 05-CV-4081, 2005 WL 2469668 (D.N.J. Oct. 6, 2005), is instructive. There, the court refused to consider arguments based upon documents, submitted for the first time on reply, on an issue with respect to which the movant carried the burden of proof. The plaintiff sought a preliminary injunction enjoining defendants from using a service mark. In

connection with its motion for a preliminary injunction, plaintiff bore the burden to “make a *prima facie* showing of a reasonable probability that it [would] prevail on the merits of the claim.” *Id.* at \*2 (citation omitted). In order to prevail on the underlying claim – trademark infringement – the plaintiff “must show that a defendant’s use of a similar mark . . . causes a likelihood of confusion,” which can be demonstrated by evidence of “actual confusion.” *Id.* (citation omitted). Plaintiff submitted a survey as purported evidence of actual confusion for the first time on reply, which the court refused to consider:

[P]laintiff introduced the survey in its reply brief, not its moving brief. This maneuver deprived the defendants of a meaningful opportunity to respond within the normal course. As such, the Court will disregard this “newly minted” evidence.

*Id.* at \*7.

Likewise, in *Brennan v. AT & T Corp.*, No. 04-CV-433-DRH, 2006 WL 306755 (S.D. Ill. Feb. 8, 2006), the court granted a motion to strike new documents, including affidavits, submitted for the first time on reply:

[h]ere, Defendant . . . supports earlier arguments with substantial new evidence. . . . This evidence consists of two new declarations and a total of nineteen new exhibits . . . . Defendant offers no good reason or exceptional circumstance that prevented it from filing these materials with its original motion. Nonetheless, it relies heavily on this evidence in its reply brief . . . . The Court determines that this new evidence must be stricken . . . . To now allow Defendant the benefit of additional evidence without offering Plaintiffs a corresponding opportunity to respond would be unfair to Plaintiffs, particularly considering the relative volume and import of the new evidence submitted on reply.

*Id.* at \*8; *see also Ballas*, 41 F. Supp. 2d at 533 (“[a] moving party may not raise new issues and present new factual materials in a reply brief that it should have raised in its initial brief”); *Elizabethtown Water Co. v. Hartford Cas. Ins. Co.*, 998 F. Supp. 447, 458 (D.N.J. 1998); *Bayer AG*, 129 F. Supp. 2d at 716-17 (striking new arguments raised for the first time in a reply brief); *United States ex rel. Englund v. Los Angeles Cty.*, No. Civ. S-04-282LKKJFM, 2005 WL 2089216, at \*6 n.26 (E.D. Cal. Aug. 30, 2005) (striking new exhibits submitted in connection with the defendant’s reply brief, as well as arguments based on the new exhibits, on the grounds that “[i]t is improper for a moving party to introduce new facts or different legal arguments in the reply brief than those presented in the moving papers”) (citation omitted); *A’Ku v. Motorola, Inc.*, No. 97 C 4728, 1999 WL 63694, at \*3 n.2 (N.D. Ill. Feb. 4, 1999) (“[d]efendant filed the exhibit to support the December 1996 filing date along with its reply brief. Of course, it is unfair for the court to consider new evidence at this time”), *aff’d*, 202 F.3d 272 (TABLE), 1999 WL 962300 (TEXT IN WESTLAW), *cert denied*, 529 U.S. 1071 (2000).

As in all of the foregoing decisions, Plaintiffs’ newly submitted arguments, and documents they are based on, should be stricken or disregarded. A party seeking class certification “bears the burden of proving that the action satisfies all four threshold requirements set forth in Federal Rule of Civil Procedure 23(a) and also falls within one of the three categories of Rule 23(b).”<sup>2</sup>

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<sup>2</sup> Rule 23(a) provides that a class may be certified “only if (1) the class is so numerous that joinder of all members is impracticable[;] (2) there are questions of law or fact common to the class[;] (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class[;] and (4) the representative parties will fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a). These requirements are generally known as numerosity, commonality, typicality and adequacy of representation. In addition to the requirements of Rule 23(a), a plaintiff seeking to certify a class must

*In re Kulicke & Soffa Indus., Inc. Sec. Litig.*, No. 86-1656, 1990 WL 1478, at \*2 (E.D. Pa. Jan. 9, 1990). It is well-settled that a class cannot be certified unless a plaintiff can meet its burden to satisfy the requirements of Fed. R. Civ. P. 23(a) and 23(b). *Davis v. Romney*, 490 F.2d 1360, 1366 (3d Cir. 1974). In order to meet this burden, “[t]he plaintiff cannot rely solely on the allegations of the complaint, but must provide sufficient information on which the court can make a determination.” *Petrolito v. Arrow Fin. Servs., LLC*, 221 F.R.D. 303, 307 (D. Conn. 2004); *see also Locaro v. Chicago Commodity Corp.*, No. Civ. A. 89-1206, 1990 WL 74250, at \*1 (E.D. Pa. May 31, 1990) (*rejecting* plaintiffs’ contention that “the allegations of the complaint itself are sufficient to support class certification”); *Cornn v. United Parcel Serv., Inc.*, No. C03-2001 TEH, 2005 WL 2072091, at \*2 (N.D. Cal. Aug. 26, 2005) (“The party seeking certification must provide facts to satisfy these requirements, and simply repeating the language of the rules in its moving papers is insufficient”); *Unger v. Amedisys, Inc.*, 401 F.3d 316, 325 (5th Cir. 2005) (“[w]hen a court considers class certification . . . it must engage in thorough analysis, weigh the relevant factors, require both parties to justify their allegations, and base its ruling on admissible evidence”). No such evidence was submitted with Plaintiffs’ opening submissions on class certification.<sup>3</sup>

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demonstrate that the action qualifies for treatment as a class action under one of the three subdivisions of Rule 23(b), *i.e.*, the predominance and superiority requirement of Rule 23(b)(3). Fed. R. Civ. P. 23(b)(3).

<sup>3</sup> Despite having the burden to establish that the four Rule 23(a) requirements have been met, Plaintiffs submitted “evidence” with their moving papers that addressed at most only two prerequisites to class certification (numerosity and adequacy of representation) -- the résumés of Lerach Coughlin Stoia Geller Rudman & Robbins, LLP and Scott and Scott, LLP and excerpts from Pharmacia Corporation’s 1999, 2000 and 2001 reports on Form 10-K filed with the SEC. Having failed to submit evidence with respect to the other prerequisites to class certification with their moving papers, Plaintiffs should be prohibited from doing so for the first time in connection with their reply papers. While Plaintiffs contend that “there is no controlling authority that defines the quantum of evidence” that must be presented in support of a



**1. Plaintiffs Did Not Meet Their Burden To Establish Predominance And They Cannot Attempt To Meet That Burden By Submitting New Materials For The First Time On Reply**

In order to satisfy Rule 23(b)(3)'s predominance standard, Plaintiffs must establish that "questions of law or fact common to the members of the class predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). Plaintiffs must establish predominance with respect to each element of claims brought under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). See *Johnston v. HBO Film Mgmt., Inc.*, 265 F.3d 178, 186-87 (3d Cir. 2001). An essential element of a claim under Section 10(b) is that the plaintiff establish reliance – "that defendants' conduct caused [the plaintiff] to "engage in the transaction.""<sup>4</sup> *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 174 (3d Cir. 2001) (citation omitted). If each plaintiff must demonstrate reliance individually, instead of on a class-wide basis, common issues do not predominate. *Id.* at 172.

Here, Plaintiffs purport to satisfy the predominance requirement of Rule 23(b)(3) by application of the "fraud on the market" theory.<sup>4</sup> Pls' Memo at 16 n.4. However, application of the fraud on the market presumption is not automatic. "To gain the benefit of the presumption, a plaintiff must prove '(1) that

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motion for class certification, Pls' Reply at 31, Plaintiffs submitted *no evidence whatsoever* on several of the prerequisites for class certification.

<sup>4</sup> Under appropriate circumstances, the "fraud on the market" theory allows plaintiffs asserting claims under Section 10(b) of the Securities Exchange Act of 1934 to satisfy the essential element of reliance without proving direct reliance on an alleged misrepresentation on the basis of a rebuttable presumption of reliance, which is based on the theory that all publicly available information is reflected in the market price of a security and the investor relied on the integrity of the market price. See *Basic Inc. v. Levinson*, 485 U.S. 224, 246-47 (1988).

the defendant made public misrepresentations; (2) **that the misrepresentations were material**; (3) that the shares were traded on an efficient market'; and (4) that the plaintiffs purchased the shares after the misrepresentations but before the truth was revealed." *Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 364 (4th Cir. 2004) (emphasis added) (*quoting Basic*, 485 U.S. at 248 n.27). For purposes of assessing the applicability of the fraud on the market theory, the Third Circuit determines the materiality of an alleged misstatement by "'looking to the movement, in the period immediately following disclosure, of the price of the firm's stock.'" *In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005) (*quoting Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000)).

Plaintiffs, who bear the burden of demonstrating that they are entitled to the benefit of the fraud on the market presumption of reliance, submitted no evidence with their moving papers on this issue, including evidence to establish that the alleged misrepresentations were material.<sup>5</sup> Only on reply do Plaintiffs proffer the Hakala Declaration, which declares that its "**primary purpose . . . is to provide an event study and analysis which demonstrates that the alleged non-disclosure of certain information . . . was material to investors.**" Hakala Decl. ¶ 6 (emphasis added). Notwithstanding the serious infirmities of the Hakala Declaration, this is precisely the type of document Plaintiffs were required to have submitted with their moving papers, and they offer no explanation for their failure

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<sup>5</sup> Plaintiffs' failure to submit evidence regarding the materiality of the alleged misstatements in question is particularly egregious because they have known from almost the inception of this action that Defendants take the position that the alleged misstatements are not material. In Defendants' memorandum of law in support of their motion to dismiss the Complaint, dated December 22, 2003, Section I.A. is entitled "Defendants Made No Material Misstatements," and Section I.A.2 is entitled "The Statements Were Not Material." *See id.* at 18-21, 26-029.



to do so. Under these circumstances, the Hakala Declaration, and all arguments based upon it, should be stricken and not considered by the Court. *See Brennan*, 2006 WL 306755, at \*\*8-9 (granting motion to strike affidavits and other evidence submitted for the first time on reply); *M.D. On-Line*, 2005 WL 2469668, at \*7 (disregarding evidence submitted for the first time on reply); *Ballas*, 41 F. Supp. 2d at 533 (“[a] moving party may not raise new issues and present new factual materials in a reply brief that it should have raised in its initial brief”); *A’Ku*, 1999 WL 63694, at \*3 n.2 (“Defendant filed the exhibit to support the December 1996 filing date along with its reply brief. Of course, it is unfair for the court to consider new evidence at this time”).<sup>6</sup>

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<sup>6</sup> Indeed, Hakala has held himself out as a putative expert on myriad issues in other matters. In these various contexts, however, Hakala’s techniques, thoroughness and reliability have been repeatedly criticized by courts throughout the nation. Hakala’s proffered opinion on shareholder damages has been rejected and stricken, based upon a finding that his methodologies were inconsistent with the federal securities laws. In light of Plaintiffs’ submission of the Hakala Declaration only on reply, Defendants have not had the opportunity to challenge Hakala’s methodology, let alone his conclusions. *See Bell v. Fore Sys., Inc.*, No. Civ. A. 97-1265, 2002 WL 32097540, at \*\*3-4 (W.D. Pa. Aug. 2, 2002). In *In re Enron Securities, Derivative & ERISA Litigation*, the court declined to consider Hakala’s affidavit on “suspicious” insider trading for the purposes of assessing plaintiff’s compliance with pleading requirements, but went on to state that it “cannot help but note” plaintiff’s failure to address challenged instances where Hakala’s statistical methodologies for “flagging” purportedly suspicious sales “imply a contrary result to that Lead Plaintiff attempts to plead.” *Newby v. Enron Corp. (In re Enron Corp. Sec., Deriv. & ERISA Litig.)*, 258 F. Supp. 2d 576, 615 n.38 (S.D. Tex. 2003). The Bankruptcy Court for the Northern District has held that Hakala’s business valuation calculations were “not supported by the evidence.” *Mims v. Kennedy Capital Mgmt., Inc. (In re Performance Nutrition, Inc.)*, 239 B.R. 93, 107-08 (Bankr. N.D. Tex. 1999). The district court agreed that “Hakala’s opinion and his estimate of the value of PNI’s assets were flawed. . . .” *Roth v. Mims*, 298 B.R. 272, 291 (N.D. Tex. 2003). The United States District Court for the Southern District of Mississippi has similarly rejected Hakala’s opinion as “not consistent with the facts of this case,” *Smith v. United States*, 923 F. Supp. 896, 904 (D. Miss. 1996), as have several other courts. *See, e.g., Barnes v. Commissioner*, 76 T.C.M. (CCH) 881, 1998 WL 795085, at \*7 (1998) (Tax Court concluded that Hakala “did not adequately consider” relevant factors, did not conduct adequate factual investigation, and improperly excluded certain comparable companies from his stock valuation analysis); *Bausch & Lomb Inc. v. Commissioner*, 71 T.C.M. (CCH) 2031, 1996 WL 64832, at \*27 (1996) (Tax court expressed “reservations” about Hakala’s work and ruled that it was “not persuaded . . . of the reliability and accuracy” of his report); *Avis Indus. Corp. & Subs. v. Commissioner*, 70 T.C.M. (CCH) 641, 1995 WL 535972, at \*13 (1995) (Tax Court found that Hakala’s

**2. Plaintiffs Did Not Meet Their Burden To Establish The Length Of The Class Period And They Cannot Attempt To Meet That Burden By Submitting New Materials For The First Time On Reply**

Plaintiffs also bear the burden to establish the appropriate class period. *See In re Linerboard Antitrust Litig.*, 203 F.R.D. 197, 221 (E.D. Pa. 2001) (“As with all other aspects of plaintiffs’ claims at [the class certification] stage of the litigation, the length of the class period must have some factual support”), *aff’d*, 305 F.3d 145 (3d Cir. 2002), *cert. denied sub nom.*, 538 U.S. 977 (2003). However, Plaintiffs submitted no documents with their moving papers to support their assertion that the class period should continue until June 1, 2002. Plaintiffs’ failure to do so is particularly egregious because they have known, since almost the inception of this case, of Defendants’ position that the class period should end no later than February 6, 2001, the date on which the so-called “truth” about Defendants’ alleged misrepresentations was publicly disclosed on the FDA website. In fact, in response to Defendants’ arguments in that regard, Magistrate Judge Bongiovanni issued an order dated July 14, 2004, which, *inter alia*, defined the relevant period for producing documents in discovery as ending as of February 2001, unless the Court certified a class ending at a later date.

On reply, Plaintiffs offer the Wright Declaration as purported support of the appropriate duration of the class period. Dr. Wright opines as to **when he believes** the “truth” was revealed, *i.e.*, when the class period should close. *See* Wright Decl. ¶¶ 29-31. Plaintiffs also submit the Confidential Documents as

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conclusions were not “totally reliable. Hakala’s sample size was small and, given the complexity and diversity of petitioner, the 25 companies selected by Hakala were of doubtful similarity to petitioner”).

purported support for the fact that the appropriate class period extends beyond February 6, 2001. If Plaintiffs believe that the Wright Declaration and the Confidential Documents support their position, Plaintiffs were required to have submitted such materials with their moving papers. For the same reasons set forth above with respect to the Hakala Declaration, the Court should strike or refuse to consider the Wright Declaration and the Confidential Documents.

**B. The Confidential Documents Should Also Be Stricken Because They Were Submitted In Violation Of Local Rules 5.2 & 7.1(b)(3)**

Local Rule 7.1(b)(3), which governs motions filed electronically, requires compliance with this Court's Electronic Case Filing Policies and Procedures, which provide that "sensitive information should not be included in any document filed with the court *unless such inclusion is necessary and relevant to the case.*" ECF 18 (emphasis added); L. Civ. R. 5.2 n.18. As set forth below, the Confidential Documents submitted by Plaintiffs are irrelevant to any aspect of Plaintiffs' motion to certify a class and they should be stricken.

Plaintiffs' proposed class period begins April 17, 2000 and ends June 1, 2002. According to Plaintiffs, the class period should extend until June 1, 2002 because on that date the British Medical Journal published an *editorial* in which author Peter Jüni "accused defendants *for the first time* of fraudulently presenting the CLASS data[]," and opined that there was no "legitimate" scientific basis for the alleged misrepresentations.<sup>7</sup> Pls' Reply at 3, 11, 15-17. Plaintiffs claim that

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<sup>7</sup> Notwithstanding Plaintiffs' efforts to extend the purported class period – and as argued by Defendants in their opposition to Plaintiffs' motion for class certification – Plaintiffs' motion should be *denied in its entirety* because Plaintiffs have utterly failed to satisfy the requirements for class certification pursuant to Fed. R. Civ. P. 23. See Defs Opp. at 13-26.

the Confidential Documents are relevant because they supposedly corroborate Jüni's opinions and demonstrate that Defendants acted with "bad faith." Pls' Reply at 11, 15.

This argument completely misses the point. For purposes of class certification, the issue *is not* whether Jüni's accusations and opinions are right or wrong, or whether on February 6, 2001, the public was aware of Defendants' alleged motives to supposedly commit fraud. Instead, the relevant issue for purposes of determining when the class period should close is the date on which the "true" facts that allegedly had been concealed by Defendants were disseminated to the market.

Information is curative when it places the plaintiff on inquiry notice of the alleged fraud. *Vitiello v. Cicconi (In re Data Access Sys. Sec. Litig.)*, 103 F.R.D. 130, 144 (D.N.J. 1984) ("[the press release] . . . constitute[d] a retraction of [defendants'] earlier . . . projections") (citing *Peil v. National Semiconductor Corp.*, 86 F.R.D. 357, 369 & n.12 (E.D. Pa. 1980) ("release . . . constitute[d] a sufficient inquiry notice . . .")). The test of whether or not curative information has been released is "a preliminary merits determination whether the facts which underlie the gravamen of plaintiffs' complaint continue to represent a reasonable basis on which the individual purchaser on the market would rely." *Id.* at 143.

The gravamen of Plaintiffs' Complaint is that Defendants violated Sections 10(b) and 20(a) of the Exchange Act by allegedly making misrepresentations in connection with the reporting of data from the Celecoxib

Long-Term Arthritis Safety Study (the “CLASS study”).<sup>8</sup> Plaintiffs allege that Defendants misrepresented the results of the CLASS study (1) by reporting the results based on 6 months of data, as opposed to using longer-term data that was available, (2) by reporting the study results in part based on how Celebrex fared in comparison to ibuprofen and diclofenac based on a “combined endpoint” of symptomatic ulcers (a “secondary endpoint”) in addition to ulcer complications (the “primary endpoint”), (3) by not following a prespecified plan for statistical analysis of the primary endpoint, which called for (i) an analysis of the Celebrex v. ibuprofen and diclofenac, combined, and then (ii) an analysis of Celecoxib v. ibuprofen and of Celebrex v. diclofenac, individually; and (4) because when “[a]nalyzing the CLASS study data pursuant to the original protocol, meaning 12 and 15 months of data compared head-to-head and in combination for ulcer-related complications, Celebrex does not offer greater GI safety than traditional NSAIDS.” Compl. ¶ 46.

As described in the Expert Report of Dr. Timothy Cragin Wang, (which was submitted along with Defendants’ Opposition Brief) and as admitted in the Expert Report of Plaintiffs’ expert Dr. James Wright, the “true” *facts* about each of the alleged factual misrepresentations set forth above were known to the

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<sup>8</sup> Celebrex is an NSAID, or nonsteroidal anti-inflammatory drug, used primarily to alleviate the pain and inflammation caused by arthritis. Unlike traditional generic NSAIDs, which inhibit both the COX-1 and COX-2 enzymes, Celebrex is a selective COX-2 inhibitor, which previous studies had shown to have a superior gastrointestinal (“GI”) safety profile than traditional NSAIDs. The United States Food and Drug Administration (the “FDA”) requires that all NSAIDs carry a warning label alerting physicians and consumers to, among other things, the potential GI side-effects associated with those medications. The CLASS study was commissioned by Pharmacia to support a supplemental New Drug Application (“sNDA”) for FDA approval of revised labeling without the Standard GI Warning Label. Defs Opp. at 6.



market no later than February 6, 2001, when information about CLASS was posted on the FDA website.<sup>9</sup> Indeed, Dr. Wright concedes that:

From the information available on the FDA's website on February 6, 2001, the astute observer could discern from the FDA reports that the CLASS study lasted longer than six months, and that data from the entire study period failed to demonstrate with statistical or clinical significance any GI safety advantage for Celebrex compared to diclofenac or ibuprofen, either with respect to the pre-determined primary endpoint of complicated ulcers or the combined endpoint of complicated and symptomatic ulcers. The FDA also discussed that Pharmacia's "combined" endpoint was a post-hoc, retrospective analysis, was not an endpoint of the CLASS study, and did not follow the study protocols.

Wright Decl. ¶ 22.<sup>10</sup>

Because the "true" facts about CLASS were publicly revealed to the market no later than February 6, 2001, it was unreasonable, as a matter of law, for Plaintiffs to have continued to rely on what Plaintiffs have wrongly characterized as Defendants' alleged prior misrepresentations. As such, the class period must end no later than February 6, 2001.<sup>11</sup> *See Cohen v. Uniroyal, Inc.*, 77 F.R.D. 685,

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<sup>9</sup> See Defs Opp. at 30-34; Wang Report ¶¶ 45-48.

<sup>10</sup> There is no substantial dispute between the parties' respective experts regarding the extent of the factual information that was publicly available as of February 6, 2001. Dr. Wright's opinion echoed that of Defendants' expert, Dr. Timothy Wang, who offered his opinion that "the posting of the Briefing Document and the FDA Staff Review Documents on the FDA website, as well as the public statements made during the FDA Arthritis Advisory Committee hearing, publicly stated each of Defendants' alleged misrepresentations regarding the results of CLASS." Wang Report ¶ 45.

<sup>11</sup> Plaintiffs' purported expert on materiality, Prof. Hakala, supports Defendants' contention that the information disclosed on February 6, 2001 and immediately thereafter during the FDA public hearings on February 7, was curative. For example, Hakala opines that "[t]he news by the afternoon of February 7 and the evening of February 7, 2001 *was sufficiently clear to begin to cause a significantly negative reaction*. As a result, Pharmacia's share price fell a relative 3.1% (highly statistically significant) in trading on February 7, 2001 and fell another 5.6% on February 8, 2001 (highly statistically significant).

688, 696 (E.D. Pa. 1977) (class period ends and subsequent reliance unreasonable after date when “many of the material facts which form the gravamen of th[e] complaint were disclosed to the public for the first time in an article about [defendant] which appeared in Forbes Magazine”); *In re ORFA Sec. Litig.*, 654 F. Supp. 1449, 1452 (D.N.J. 1987) (closing class period and finding reliance unreasonable after date of publication of “Barron’s article which alleged information contradictory to [defendant’s past press releases and reports”]; *In re Kulicke & Soffa Indus.*, 1990 WL 1478, at \*5 (class period ends and subsequent reliance unreasonable after publication of press release stating that allegedly false sales forecast was “overly optimistic”).<sup>12</sup>

Plaintiffs contend that notwithstanding the admitted disclosure of all *facts* necessary to reveal the truth about the alleged misrepresentations, the class period should not close on February 6, 2001 because at that time there was no “strong [published] indication that Pharmacia may have acted in bad faith or

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Overall, Pharmacia’s share price lost approximately 9.0% of its relative value between February 6 and February 8, 2001 (extremely significant).” Hakala Decl. ¶ 40 (emphasis added).

<sup>12</sup> Plaintiffs also contend that the class period should extend beyond February 6, 2001 because, notwithstanding public disclosure of all underlying *facts* necessary to reveal the alleged misrepresentations, only the Jüni Editorial revealed that Defendants “falsely portray[ed] . . . [their] omission of the post-six month data from the JAMA article [on the basis of informative censoring] as a legitimate scientific decision made in good faith.” However, Jüni’s supposed “revelation” regarding the merits of Defendants’ reliance on informative censoring is the same criticism – almost word-for-word – as was offered by FDA Statistician, Dr. Hong Laura Lu, in the “Statistical Reviewer Briefing Document for the Advisory Committee,” which was published on the FDA website on February 6, 2001. *Compare* Dreier Decl., Ex. 26 at 1288 *with* Dreier Decl., Ex. 12 at 8-9. In any event, Plaintiffs’ reliance on the Jüni Editorial as supposed evidence of the *fact* that the Defendants’ basis for reporting six-month data from CLASS (*i.e.*, informative censoring) was “utterly false” and could not be the subject of “legitimate scientific debate” is unavailing. First, Jüni’s opinion is nothing more than that, and it neither proves nor offers any *facts*. Second, the editorial itself is part of the “legitimate scientific debate” over CLASS. Indeed, in a February 8, 2003 letter to the editor of the BMJ, statistician Jonathan Deeks responded to the Jüni editorial and opined that contrary to Jüni’s conclusions, “[t]he six month data provide the most robust findings from [CLASS],” and that aspects of the Jüni editorial were “*misleading*.” Jonathan J. Deeks, *et al.*, *Author’s Reply*, 326 BMJ 335 (Feb. 8, 2003) (emphasis added).

fraudulently.” Wright Decl. ¶ 29. According to the Plaintiffs, the Confidential Documents allegedly demonstrate this “bad faith.” But, even assuming, *arguendo*, that the Confidential Documents are evidence of bad faith (which they are not), they are irrelevant to the determination of the appropriate class period.

Neither the Jüni Editorial nor the Confidential Documents that supposedly corroborate Jüni’s opinions and demonstrate Defendants’ “bad faith,” inform the analysis of whether Plaintiffs’ reliance on Defendants’ alleged misstatements after February 6, 2001, was reasonable in light of the undisputed public disclosure of all material facts about the results of the CLASS study. Whether Jüni’s opinions are correct and/or whether the public was aware on February 6, 2001 of Defendants’ alleged “bad faith,” is irrelevant, as a matter of law, to the determination of whether the *facts* publicly disseminated on or before February 6, 2001 constitute curative information.<sup>13</sup> As such, Plaintiffs’ are attempting to file the documents in violation of Local Rules 5.2 and 7.1(b)(3) (and this Court’s Electronic Case Filing Policies and Procedures), which clearly prohibit parties to a suit from filing sensitive information with a court “*unless such inclusion is necessary and relevant to the case,*” and they should be stricken. ECF 18 (emphasis added); L. Civ. R. 5.2, n.18.

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<sup>13</sup> Moreover, it is well-settled that the federal securities laws require disclosure of objective material facts, such as those that were revealed by the FDA on February 6, 2001, and not the pejorative characterizations or motivations which Plaintiffs claim that the Jüni Editorial and the Confidential Documents reveal. See *Lewis v. Chrysler Corp.*, 949 F.2d. 644, 651 (3d Cir. 1991) (“While management motives in changing the Plan may have been self-serving as alleged, Chrysler’s failure to disclose the management’s entrenchment scheme is not actionable under the federal securities laws”); *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (“federal securities laws do not require a company to accuse itself of wrongdoing”); *Stein v. Aldrich*, No. 78 Civ. 2364, 1980 WL 1489, at \*5 (S.D.N.Y. July 18, 1980) (“it is not deceptive to fail to “characterize” th[e] facts with “pejorative nouns and adjectives,” or to fail to verbalize all adverse inferences expressly”) (citation omitted).



**C. In The Alternative, Defendants Should Be Granted Leave To File  
A Surreply**

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Local Rule 7.1(d)(6) permits surreplies with “permission of the Judge or Magistrate Judge to whom the case is assigned.” L. Civ. R. 7.1(d)(6). Accordingly, if this Court declines to strike Plaintiffs’ new arguments and evidence, the Court should afford Defendants the opportunity to submit a surreply to respond to Plaintiffs’ new arguments and evidence. *Rochlin v. Cincinnati Ins. Co.*, No. IP00-1898-CH/K, 2003 WL 21852341, at \*9 (S.D. Ind. July 8, 2003) (“Because defendant submitted additional evidence with its . . . reply brief, plaintiffs were entitled to respond in a surreply as a matter of elementary fairness”); *Glenmont Hill Assocs. v. Montgomery Cty., Md.*, 291 F. Supp. 2d 394, 396 n.1 (D. Md. 2003) (surreply granted because the “[d]efendants raised new arguments in their reply”); *North Carolina Shellfish Growers Ass’n v. Holly Ridge Assocs., LLC*, 200 F. Supp. 2d 551, 554 (E.D.N.C. 2001) (“Plaintiffs are entitled to file a surreply in order to respond to” new evidence attached to the defendant’s reply brief); *Alexander v. FBI*, 186 F.R.D. 71, 74 (D.D.C. 1998) (granting surreply in order for the plaintiffs “to contest matters presented to the court for the first time in the form of [the movant’s] declaration” submitted on reply).

POINT II

**IF NOT STRICKEN, THE CONFIDENTIAL  
DOCUMENTS SHOULD BE SEALED**

**A. The Plaintiffs Should Not Be Permitted To Evade The Protective Order By Submitting Irrelevant Confidential Documents In Connection With Their Class Certification Reply Papers**

On July 26 2004, Magistrate Bongiovanni entered a Stipulation And Protective Order which allows the parties to designate documents produced in discovery as “confidential,” and, thereby, prohibit public dissemination of documents containing “sensitive information which a party deems confidential.” Order at 1. The Protective Order provides that it “govern[s] all documents . . . produced or disclosed during” this action. Order at 2 ¶ 1. Here, Plaintiffs are attempting to subvert the provisions of the Protective Order, to which they stipulated and which was entered as an order of the Court, by submitting irrelevant Confidential Documents in connection with their reply in further support of their motion for class certification, and arguing that those Documents are not in fact confidential under the standards articulated in Local Rule 5.3.

The determination whether the Confidential Documents are appropriately afforded the protection of the Protective Order, should be made by reference to the standard of confidentiality set forth in the Protective Order itself, and not pursuant to Local Rule 5.3. Any other result effectively eviscerates the protections established by this Court when it entered the Protective Order by the application of a different standard that is inapplicable under the circumstances because the Confidential Documents are irrelevant. *See* Local Rules 7.1(b)(3) & 5.2, n.18 (prohibiting parties to a suit from filing sensitive information with a court

“unless such inclusion is necessary and relevant to the case”). Under the Protective Order, the Confidential Documents contain “sensitive information that [Defendants] deem confidential,” and they are not relevant, and thus should be not be filed at all. Order at 1. These documents are non-public, internal emails and draft meeting minutes reflecting back-and-forth discussion and analysis concerning the CLASS study, the publication of CLASS data, upcoming FDA meetings, and the like. All this non-public information would, if publicly disclosed, reveal elements of Pharmacia/Pfizer’s internal process for the design, conduct, analysis and evaluation of clinical studies and scientific data. As a result, these Confidential Documents are precisely the type of material that is entitled to the protections afforded under the Protective Order entered by this Court.

**B. The Confidential Documents Should Be Sealed Pursuant To Local Rule 5.3**

Even under the standard articulated in Local Rule 5.3, the Confidential Documents should be sealed. In order for documents to be sealed pursuant to Local Rule 5.3, the proponent of the sealing order must describe (a) the nature of the materials or proceedings at issue, (b) the legitimate private or public interests which warrant the relief sought, (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available. L. Civ. R. 5.3(c)(2).

**1. Public Disclosure Of The Confidential Documents Would Cause A Clearly Defined And Serious Injury, And There Are Legitimate Public And Private Interests That Warrant Sealing The Confidential Documents**

Exhibits A, K, L, O, P, Q and R to the Pearlman Declaration are confidential internal Pharmacia/Pfizer documents that contain self-critical analysis of the CLASS study by Pharmacia clinicians and researchers. As such, the public

dissemination of these documents would cause a “clearly defined and serious injury,” as well as curb subjective analysis and professional criticism that, as a legitimate public interest, is crucial to the pharmaceutical industry’s ability to develop new, safe and effective drugs.

Courts in this district recognize the self-critical analysis privilege. *Bracco Diagnostics, Inc. v. Amerhsam Health Inc.*, No. Civ. A.03-6025, 2006 WL 2946469, at \*3 (D.N.J. Oct. 16, 2006). This privilege “protects from discovery certain critical self-appraisals.” *Reichhold Chems., Inc. v. Textron, Inc.*, 157 F.R.D. 522, 524 (N.D. Fla. 1994). “The purpose of the privilege is to foster self-evaluation and the benefits derived therefrom.” *Brunt v. Hunterdon Cty.*, 183 F.R.D. 181, 185 (D.N.J. 1998); *Robbins v. Provena Saint Joseph Med. Ctr.*, No. 03 C 1371, 2004 WL 502327, at \*1 (N.D. Ill. Mar. 11, 2004) (“The privilege is granted on the premise that disclosure of documents reflecting candid self-examination will deter or suppress socially useful investigation and evaluations”). The self-critical analysis privilege has been recognized in a variety of actions in which confidentiality is ““essential to the free flow of information and . . . *the free flow of information is essential to promote recognized public interests.*”” *Harding v. Dana Transp., Inc.*, 914 F. Supp. 1084, 1100 (D.N.J. 1996) (emphasis added; citation omitted).

The self-critical analysis privilege recognizes that production of documents containing self-critical analysis to an adverse party would cause a “clearly defined and serious injury.” If production *to an adverse party* alone can cause “clearly defined and serious injury,” certainly *widespread public dissemination* of confidential documents containing self-critical analysis would

also cause such injury. Thus, even though the Confidential Documents have not been withheld from production on the basis of the self-critical analysis privilege (they were produced subject to a strict confidentiality order), they should be protected from public dissemination by a sealing order. Indeed, the New Jersey Supreme Court has held that even when a court finds that documents cannot be withheld from production on the basis of the self-critical analysis privilege, “it should take adequate protective measures to ensure **maximal confidentiality** given the necessity of disclosure.” *Payton v. New Jersey Tpk. Auth.*, 691 A.2d 321, 333 (N.J. 1997) (emphasis added); *see, e.g., Bracco Diagnostics*, 2006 WL 2946469, at \*3 (“constructive professional criticism cannot occur in an atmosphere of apprehension . . .” and “[t]he value of self critical evaluations would be destroyed if not shielded from the discovery process”) (citation omitted); *Robbins*, 2004 WL 502327, at \*2 (applying privilege to materials “used for the purpose of evaluating and improving patient care”).

In connection with their reply papers, Plaintiffs have submitted (1) five internal e-mails containing internal company analysis of confidential scientific information,<sup>14</sup> (2) a set of “meeting minutes” reflecting discussion of the CLASS data in preparation for a presentation to the FDA Arthritis Advisory Committee<sup>15</sup> and (3) a draft “CLASS summary” document reflecting internal preparation for discussions with the FDA regarding potential Celebrex label changes.<sup>16</sup> Each of

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<sup>14</sup> See Pls’ Exs. A, L, O, P and R. These documents were designated confidential under the Protective Order that was stipulated to by both parties and entered into the record by Magistrate Judge Bongiovanni on July 26, 2004.

<sup>15</sup> See Pls’ Ex. Q. This document was also designated confidential under the Protective Order.

<sup>16</sup> See Pls’ Ex. K. This document was also designated confidential under the Protective Order.

these documents contains confidential, self-critical analysis that should be protected from public disclosure.<sup>17</sup> The internal e-mails (Exs. A, L, O, P and R), for example, discuss, among other things, subjective analysis regarding the design, conduct and results of the CLASS study, as well as debate with respect to a draft manuscript presenting CLASS data (a manuscript drafted *subsequent to both the publication of CLASS results in JAMA in September 2000 and the FDA Arthritis Advisory Committee's decision, in February 2001, to decline to recommend a change to the warning for Celebrex based upon the CLASS study data*). The draft minutes (Ex. Q) of a January 24, 2001 meeting of Pharmacia clinicians in preparation for an FDA Arthritis Advisory Committee hearing and the CLASS summary document (Ex. K) reflect the clinicians' internal analysis regarding, among other things, what data represents the most valid safety profile of Celebrex, and their opinions regarding study design and conduct. Moreover, the clinicians discussed what they believed to be the inherent scientific challenges and difficulties presented by the CLASS study.

These confidential emails, meeting minutes and CLASS summary document contain precisely the type of subjective analysis and professional criticism that is crucial to the pharmaceutical industry's ability to develop new, safe and effective drugs, and it should be encouraged, not discouraged by the threat of public disclosure.

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<sup>17</sup> Exs. C and S to the Pearlman Declaration are the same document (the final report for the CLASS study). The document contains information thereafter made available on the FDA website. Consequently, Defendants withdraw the confidentiality designation with respect to Exs. C and S.

2. **A Less Restrictive Alternative To Filing Under Seal Is Not Available**

As discussed above, the documents identified by Plaintiffs are confidential and should, therefore, be filed under seal. In this situation, the only alternative to filing the confidential documents under seal would be to redact from the documents all references containing confidential information. However, such alternative is impractical because most – *if not all* – of the documents' pages would require extensive redactions.<sup>18</sup>

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<sup>18</sup> In that event, Defendants would respectfully request the opportunity to present the appropriate redactions.



**CONCLUSION**

For the reasons set forth above, the Court should (1) grant Defendants' cross-motion to strike materials offered by the Plaintiffs for the first time with their Reply and all arguments based on such newly submitted materials, or in the alternative, grant Defendants' leave to file a surreply, and, (2) if not stricken, seal the Confidential Documents.

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Respectfully submitted,

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